Incorporating the Patient Voice in the Review of Clinical Research Materials

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At the conclusion of the presentation, you should be able to:

1. **Summarize** the value of incorporating the target audience in the review of patient facing materials

2. **Apply learnings** from patient feedback to increase readability, decrease bias and eliminate the appearance of promotion in patient facing materials

3. **Consider** ways in which to include the community in the review of patient facing materials

4. **Analyze** the selection of appropriate stakeholders in the review process
About CISCRP

Center for Information and Study On Clinical Research Participation

• Independent, 501(C)(3) non-profit
• Boston-based
• Globally active
• Founded in 2003
  ❖ Dedicated to engaging the public and patients as partners in clinical research
  ❖ Collaborate with foundations, associations, advocacy groups, industry, academic institutions, government agencies
Patient Centricity: Definitions, Valuation and Regulation
“Defining” Patient Centricity

❖ **Patient engagement:** Activities that involve patient stakeholders sharing their experiences, perspectives, needs, and priorities.

❖ **Patient-centric trials:** Trials that are designed specifically around patient needs, include patient reported outcome measures, or are co-designed with patients.

❖ **Patient-centered / Patient-focused:** A systematic approach to help ensure that patients’ experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into the development and evaluation of medical products throughout the medical product life cycle.

❖ **Patients as Partners:** Patients/patient groups are members of the research team.

Working with patients and their communities to understand *and meet* population-specific needs across the entire lifecycle of medical product development.
Patient Centricity in Clinical Research

Meet patient needs at all stages of the research process to improve experiences, understanding, and decision-making.

Before Participation
- Receive input on study design, conduct, etc.
- Raise awareness & provide clear education
- Alert patients to trials with database technology and Health Care Practitioner engagement
- Ensure Informed Consent is clear & understood

During Participation
- Collect feedback on study conduct & experience
- Reduce burden through remote trials and concierge services
- Routinely engage & express appreciation
- Continually inform & engage participants

After Participation
- Gain feedback on study experience
- Coordinate return to standard care
- Share Aggregate and Individual Results

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Patient involvement in medicines R&D

Research Priorities
- Setting Research Priorities
  - gap analysis
  - early horizon scanning
  - matching unmet needs with research
  - defining patient-relevant added value and outcomes

Protocol Design
- relevant endpoints
- benefit/risk balance
- in-/exclusion criteria
- diagnosis procedures
- quality of life and patient reported outcomes
- ethical issues
- data protection
- mobility issues/logistics
- adherence measures

Trial steering committee
- protocol follow up
- improving access
- adherence

Information to trial participants
- protocol amendments
- new safety information

Investigators Meeting
- trial design
- recruitment
- challenges
- opportunities
- can trigger amendments

Data & Safety Monitoring Committee
- benefit/risk
- dropout issues
- amendments

Regulatory Affairs
- MAA evaluation
- EPAR summaries
- key summary of results
- package leaflet
- updated safety communication

Dissemination, Communication, Post-approval
- contribution to publications
- dissemination of research results to patient community / professionals
- post-study communication
- assessment of value
- patient-relevant outcomes
- patient priorities

Health Technology Assessment

Practical Considerations
- content
- visual design
- readability
- language
- dissemination

Informed Consent
- content
- visual design
- readability
- language
Measuring the Value of Patient Centricity

Return on Engagement (ROE)

• “Risk-adjusted financial models can assess the impact of patient engagement.”

• “Engagement activities with the potential to avoid protocol amendments and/or improve enrollment, adherence, and retention may add considerable financial value.”

Assessed the impact of patient engagement on ENPV for a typical oncology development program entering phase 2 or phase 3. Expected net present value (ENPV) is a common technique that integrates the key business drivers of cost, time, revenue, and risk into a summary metric for project strategy and portfolio decisions.

Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI’s Patient Groups and Clinical Trials Project
https://journals.sagepub.com/doi/full/10.1177/2168479017716715

• “Patient-centric trials took almost half the time to recruit participants, recruited double the number of patients, and the drug was 19% more likely to be launched.”

• “Only 5.2% of Phase II and III trials actually utilized this patient-centric approach.”

Patient-centric trials are designed specifically around patient needs, include patient reported outcome measures, or are co-designed with patients.

The Economist Intelligence Unit. 2018. The innovation imperative: the future of drug development

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Important Regulatory Developments

**FDA Patient-Focused Drug Development Guidance Series**

1. Collecting Comprehensive and Representative Input (FINAL)
2. Guidance 2: Methods to Identify What is Important to Patients (FINAL)
3. Guidance 3: Selecting, Developing or Modifying Fit-for-Purpose Clinical Outcomes Assessments


**ICH Guideline E8 (R1):**

“General considerations for clinical studies”

- **Patient Input into Study Design**
  “Consulting with patients and/or patient organisations in the design, planning and conduct of clinical studies… ultimately supports the development of medicines that are better tailored to patients’ needs”

- **Study Reporting**
  “The transparency of clinical research in drug development includes the registration of clinical trials on publicly accessible and recognised databases, and the public posting of clinical trial results”

Patient Insights: Involving the Target Audience
Patient Involvement Benefits

Ensures all materials are:

- **Engaging**: whether the structure is clear, engaging, and likely to enhance comprehension and ability to quickly locate the most relevant information.
- **Effective**: enhance comprehension and ability to navigate relevant information through effective graphic design and layout
- **Unbiased**: whether any content presents as too positive or too negative, incomplete in an important way, or is inaccurate.
- **Culturally appropriate**: whether the content is sufficiently sensitive to the needs, experiences, and expectations of the intended audience.
Involve the right stakeholders...

“Individual Patients”: personal experience of living with a disease

“Caregivers”: support individual patients

“Patient Advocates”: insight and experience of supporting a larger population of patients living with a disease

“Patient Organization Representatives”: mandated to represent and express the collective views of a patient organization on a specific issue or disease area.

“Patient Experts”: in addition to disease-specific expertise, have the technical knowledge in R&D and/or regulatory affairs through training or experience
1. Planning
   - Research and define population specific needs
   - Partner with Subject Matter Experts (include Patients & Advocates)

2. Development
   - Co-creation
   - Target Audience Review (at least!)

3. Evaluation
   - Assess and improve
   - Measure Impact
Patient Insights and Involvement Methods

- Literature Reviews
- In-depth Interviews
- Online Surveys
- Social Listening
- Advisory boards and workshops
- Co-development
### Patient and Care Partner Advisory Boards

**In-person or virtual** round table discussions to solicit **patient and caregiver feedback** on a wide range of **disease experience** and **clinical research-related topics**.

<table>
<thead>
<tr>
<th>FORMAT:</th>
<th>Structured, facilitated virtual or in-person meetings (pre-planned single meeting or series, or ad hoc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMPOSITION:</td>
<td>6 to 8+ Patients / Care Partners</td>
</tr>
<tr>
<td>TIMING/LOCATION:</td>
<td>Virtual sessions or half-day meetings in a convenient metro area</td>
</tr>
</tbody>
</table>

![Single engagements or a long-term standing resource for organizations!](image)

**DISCUSSION TOPICS:**

- Patient journey to diagnosis
- Clinical care + treatment experiences
- Perceptions of clinical research
- Protocols and study design elements
- Wearable devices
- Branding and study positioning communication (patient-facing materials)
- Topics related diversity and inclusion in research
- Informed Consent materials
- New technology solutions (Trial-specific or trial finder websites, smart packaging, virtual visits, etc.)
- Clinical trial medicine kit design and administration
Virtual Advisory Board Set-Up

- Two, 2-hour sessions (held in close succession); prefaced by a team prep meeting
- Use of video to help build rapport
- Easy-to-use conferencing platform
- Project team can raise questions in real-time to the moderator
- Strict limit on number of participants (8 max) to ensure all can voice opinions
- Pre-read materials can be sent in advance of meeting
- Advance prep calls with participants to minimize technical difficulties
- Security measures (meeting password, meeting lock, waiting room, unique meeting link, invitations only sent to participants)

Global (Non-English) Set-up:
Native-speaking moderator | Simultaneous English translation | Translation of materials
Feedback Forum

Informal: use your own team to develop, implement and execute a forum for feedback

- Use 1 hour zoom with intended audience
- Build rapport with each participant before the meeting; be sure they understand the purpose of the meeting and know how to use the technology
- Create a moderator guide; be sure you and your team are clear on the type of feedback you are requesting
- Have sample materials available to be reviewed; consider showing 2-3 versions of the same material – it’s easier to get feedback when people have something to respond to
- Be sure to close the loop with participants. Consider sharing the final version of the material so they can see how their feedback was used to improve the material
Patient / Care Partner Journey Workshops

**In-person or virtual** round table discussions to solicit **patient and caregiver feedback** on a wide range of **disease experience** and **clinical research-related topics**.

**FORMAT:** Structured, facilitated virtual or in-person meetings *(pre-planned single meeting or series, or ad hoc)*

**COMPOSITION:** 6 to 8+ Patients / Care Partners

**TIMING/LOCATION:** Virtual sessions or half-day meetings in a convenient metro area

**MAPPING EXERCISES:**
- ✔ Becoming aware
- ✔ Informed consent process
- ✔ Screening visit
- ✔ Study drug (placebo) administration
- ✔ Treatment period
- ✔ Site experiences
- ✔ Study follow-up
- ✔ Transition to standard care
Co-development: the gold standard

- Developing materials should be an interactive process
- Ideally co-developed with the audience in which the materials are intended to be used
Example: Co-development – Growth cycle of an infographic

Blacks and African Americans have been underrepresented in clinical trials.

United States population estimates by race (2019)

Clinical trial participation by race (2015-2019)

Black and African American people make up 13% of the U.S. population, but only 7% of the participants in trials for treatments approved from 2015 to 2019.

source: FDA Drug Trials Snapshot Summary Report, United States Census Bureau

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source: FDA Drug Trials Snapshot Summary Report, United States Census Bureau

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Stakeholder Involvement Practices

Create atmosphere conducive to open conversation
- Ice breaker (i.e. share favorite food, hobby, sport)
- Convey that participants are the experts
- Do not correct participants

Make all materials understandable
- Pre-read materials accompanied with clear instructions
  - Slides or packet with topics and snippets of materials they are asked to provide feedback on
  - All materials should be easy-to-use and -understand (with the exception of study protocols or other similar)

Importance of an unbiased, experienced moderator
Testing your materials
Evaluation: Access and Improve

• Flesch Kincaid Readability
• The SMOG (Simple Measure of Gobbledygook)
• The PMOSE/IKIRSCH Document Readability Formula

Assessment Tools
• CDC Clear Communication Index - Score Sheet
• “SAM” – Suitability Assessment of Materials - Form
• Patient Education Materials Assessment Tool (PEMAT) – Form

• Performance and scenario tests
• Think Out Loud
• Stoplight coding
• Paraphrase testing
• Teach Back
### Example: Identifying Key Messages

What is the purpose and importance of what you are trying to convey for a Patient Audience? For example, the study title.

- **Purpose:** introduction to the study
- **Importance:** identify the 2 most important pieces of information for them

#### The full title of your study

A 24-week treatment, multicenter, randomized, double blinded, double dummy, parallel-group, clinical trial evaluating the efficacy and safety of aclidinium bromide 400 μg/formoterol fumarate 12 μg fixed-dose combination BID compared with each monotherapy (aclidinium bromide 400 μg BID and formoterol fumarate 12 μg BID) and tiotropium 18 μg QD when administered to participants with stable chronic obstructive pulmonary disease

#### Short study title

A study to learn how 2 drugs taken together affect participants with COPD compared to taking the drugs separately.
Example: When to Use Familiar Words

When should I refer to “side effects” versus “adverse events” or “adverse reactions”?

- **Side Effects**: when there is established causality
- **Adverse Events or Adverse Reactions**: when causality is **not** established

**The Rationale:**
- The General Public understand or are familiar with the term side effects
- Clinical trial participants typically understand that adverse event or adverse reaction is indicative of definitive causality
<table>
<thead>
<tr>
<th>Technical Term</th>
<th>Plain Language Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>abdomen</td>
<td>belly, stomach</td>
</tr>
<tr>
<td>abdominal discomfort</td>
<td>belly discomfort</td>
</tr>
<tr>
<td>abdominal distension</td>
<td>swollen belly or feeling full</td>
</tr>
<tr>
<td>abdominal pain</td>
<td>belly pain</td>
</tr>
<tr>
<td>abdominal pain lower</td>
<td>belly pain below the belly button</td>
</tr>
<tr>
<td>abdominal pain upper</td>
<td>belly pain above the belly button</td>
</tr>
<tr>
<td>abnormal faeces/abnormal feces</td>
<td>abnormal stools</td>
</tr>
<tr>
<td>abnormal liver function test</td>
<td>blood test that shows your liver is not working well</td>
</tr>
<tr>
<td>abortion spontaneous</td>
<td>miscarriage</td>
</tr>
<tr>
<td>abscess</td>
<td>collection of pus</td>
</tr>
<tr>
<td>absorb</td>
<td>take in or soak up</td>
</tr>
<tr>
<td>accidental overdose</td>
<td>using more drug than prescribed by mistake</td>
</tr>
<tr>
<td>acidosis</td>
<td>too much acid in the blood</td>
</tr>
<tr>
<td>acne</td>
<td>pimples</td>
</tr>
<tr>
<td>acute</td>
<td>new, recent, sudden, urgent</td>
</tr>
<tr>
<td>acute kidney injury</td>
<td>sudden episode of kidney injury</td>
</tr>
<tr>
<td>acute myocardial infarction</td>
<td>sudden heart attack</td>
</tr>
<tr>
<td>acute pancreatitis</td>
<td>a condition where the pancreas becomes inflamed (swollen) over a short period</td>
</tr>
<tr>
<td>acute pyelonephritis</td>
<td>sudden kidney infection</td>
</tr>
<tr>
<td>acute respiratory distress syndrome</td>
<td>lung Injury that allows fluid to leak into the lungs</td>
</tr>
<tr>
<td>acute respiratory failure</td>
<td>lungs suddenly not working properly</td>
</tr>
<tr>
<td>adenocarcinoma</td>
<td>type of cancer that starts in a specific type of gland cells</td>
</tr>
<tr>
<td>administered</td>
<td>given</td>
</tr>
<tr>
<td>agranulocytosis (uh-gra-nuh-low-sai-tow-suhs)</td>
<td>extremely low number of a type of white blood cells</td>
</tr>
<tr>
<td>AIDS (acquired immunodeficiency syndrome)</td>
<td>most advanced stage of HIV infection</td>
</tr>
<tr>
<td>alanine aminotransferase (ALT) increased</td>
<td>increased level of liver protein in the blood</td>
</tr>
<tr>
<td>allergic dermatitis</td>
<td>skin rash caused by an allergic reaction</td>
</tr>
<tr>
<td>alopecia (a-luh-pee-shuh)</td>
<td>hair loss</td>
</tr>
<tr>
<td>anaemia/anemia</td>
<td>low number of red blood cells</td>
</tr>
<tr>
<td>anal abscesses</td>
<td>collection of pus near the anus</td>
</tr>
</tbody>
</table>

Sample Plain Language Glossary

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• Identify the most important communication characteristics that enhance clarity and understanding of public messages and materials
• Provides a tool for staff to develop and assess materials
General Plain Language Tips

• Word Choice
  ▪ Tone and voice – 2nd person and active voice
  ▪ Use familiar (not just “simple”) and technical terms

• Organization
  ▪ Inverted pyramid
  ▪ “Chunking” narrative
  ▪ Sentence structure

• Need to Know vs Nice to Know
  ▪ Know your Audience
  ▪ Know the purpose of the communication
  ▪ Know the purpose of the section, subsection, paragraph, and sentence!

• Balance Completeness and Ease of Understanding
Example Training: Health Literacy Workshops

Training provides:
• critical thinking skills
• how-to skills needed to develop patient and public facing materials and programs
• case studies and hands-on activities
Example: The Teach back Method

- The materials you may be given to provide to patients or the public, may not always be ideal.
- To compensate for this challenge; use the teach back method to bridge the gap.

**Step 1:** Share information

**Step 2:** Confirm understanding

**Step 3:** Rephrase or clarify if necessary, and reconfirm understanding

**Step 4:** Move on and repeat
Example: The Teach back Method (continued)

- Do you have any questions for me?
  - What two questions do you have? What can I review again for you?
- Does this make sense to you?
- Do you understand the study?
  - What study procedures need more explanation? What risks are concerning to you?
Patient & Public Insights and Patient Engagement Examples
Perceptions and Insights Global Surveys

- Measuring Clinical Research Perceptions and Experiences

- 12,400+ respondents globally
  - Past trial participants
  - Members of the public

- Biannual
  - 2021 reports now available!
  - 2021 is 4th iteration

- Publically Available Data
  - Reports (sub-group stratification)
  - Publications (longitudinal analysis)
  - Webinars

https://www.ciscrp.org/services/research-services/perceptions-and-insights-study/
Education and Awareness

✔ Enhance public awareness, literacy and understanding of clinical research with educational articles/ads

✔ Improve public perception of the clinical research volunteer

✔ Highlight the critical importance of patient diversity and inclusion within clinical trial participation

• Media Outreach
• Take-way Content (brochures, books, posters)
• Educational Videos and Webinars
• **Mission**
  - Raise clinical research awareness and literacy among the public and patient communities and recognize study participants as Medical Heroes.

• **Content and Format**
  - 8-12-page print & digital supplement with featured articles, advertisements, and a full-page ad that spreads awareness about clinical research
  - Full-page, 4-color back cover ad for sponsor logo placement

• **Publish Dates**
  - Twice a year in June and December
Patient Diversity Campaign

• Mission
  • Spreading awareness of clinical research and sharing educational initiatives with underserved minority communities. The campaign highlights the importance of diversity among clinical study participants in order to discover effective treatments for everyone.

• Content and Format:
  • Full-page, 4-color advertisement
  • Full- or half-page sponsored article

• Publish Dates:
  • Twice a year: May & October
    • Print: Atlanta Voice, Chicago Citizen, Michigan Chronicle, Philly Tribune, LaOpinion (Spanish)
    • Digital: Chicago Defender, Atlanta Daily World, News Pittsburgh Courier, Atlanta Tribune
Educational Materials

- Educational Materials
  - Brochures
  - Books
  - Videos
  - Posters
  - Infographics
  - Medical Hero Articles

- Reach a variety of audiences (numerous languages available)

- Content available in print, digital and/or to license. Co-branding and co-development available

- Content may be used for websites, patient portals, videos, or other outreach to participants or the public
Finding Treatments Together Video Series

Visit FindingTreatmentsTogether.org

A 3-part, animated, live action video series that shares how new therapies are developed, the safeguards in place, how clinical trials are adapting to be more accessible in the current environment and explains the role each person has involved in clinical research.

General Clinical Research Overview
Basics of Clinical Trial Participation
The Clinical Research Team is Similar to a Sports Team

Available in English, Spanish, and Mandarin
Educational Events: AWARE for All

Grass-roots campaign to engage and educate patients and the public in clinical research:

✔ Health and research professionals speak, exhibit and provide free health screenings

✔ 350 – 600 attendees per event

✔ 5 major US cities annually

✔ 1 international city bi-annually

✔ 2 – 4 million people reached through outreach per city (print and digital, social and mass media)
• AIC supports 25 AWARE for All events from 2020–2025
• Enables continuous improvement and refinement, guided by key outcome measures
• Increases outreach within local communities
• Engages diverse, underserved populations
Innovative Engagement

New ways to engage diverse communities:

✔ Journey to Better Health
✔ MT Pharmacy
✔ Medical Heroes Appreciation Events
  • 5K Walk/Runs
  • Virtual fitness competitions
✔ Traveling Education Exhibit
✔ Expanding into Europe and Asia
Informed Consent Innovation

• **Ensure understanding** in Informed Consent Process and improve adherence (plain > legal language)

• Create a **navigable and visually engaging** document or eConsent application (videos, TOC, headings, color, icons)

• Introduce **key information first**

• Assume no prior knowledge of clinical research

• Clear and accessible
• Support the consent process and provide a takeaway with understandable information from the protocol

• Create a navigable and visually engaging document (TOC, headings, color, icons)

• Provide information that is most important to patients

• Assume no prior knowledge of clinical research

• Clear and accessible
Thank, Engage and Unblind Participants

✔ Thank and recognize Participants for their role in advancing medical science

✔ Set expectations and provide instructions for accessing study results

✔ Share treatment assignments (unblinding)

✔ Provide educational information
  ▪ Phases
  ▪ Timelines
  ▪ Blinding
  ▪ Placebo
  ▪ Custom topics

Thank you for participating in the clinical study for [DRUG-NAME]. Your clinical study is sponsored by [CLIENT-NAME]. It is being carried out by a team of doctors, scientists, study coordinators, and study participants (across the country/in countries around the world).

Together, you make it possible to find out if the [STUDY DRUG] helps with [STUDY CONDITION].

A summary of the study results will be available at [WWW.WEB.TEL.COM].

[Thank you image]

Learn about PHASES of CLINICAL RESEARCH

Clinical research happens in four steps called "phases". The trials in each phase help answer different medical questions about a new drug or treatment. Read on to learn what happens in each phase.

What happens in each phase of clinical research?

- In Phase 1 trials, researchers and a small group of about 20-80 volunteers test a new drug. Their goal is to see how much of the drug people tolerate, how safe the drug is, and what side effects it might cause.
- In Phase 2 trials, the study drug is tested by a larger group of about 100-200 volunteers. This goal of the trial is to see how well the drug works and to keep checking to see if it is safe.
- In Phase 3 trials, the study drug is tested by hundreds or thousands of volunteers. The goal is to make sure that the drug is safe and effective and it’s going to be used in everyday life.
- In Phase 4 trials, researchers keep checking on how well the drug works, and how safe it is, after it has been approved for use by the public.

[Further information and resources available at the website mentioned above.]
Trial Results Sharing

✔ Develop and disseminate aggregate study and individual participant results

✔ Ensure results are easy-to-understand, unbiased and non-promotional

✔ Produce high-quality, professional formats
  - Plain Language Summary
  - Plain Language Summary Publication
  - Webinar
  - Video and animation

✔ Align with regulatory requirements and relevant results sharing guidelines

✔ Include graphical elements critical for clarity and comprehension
Website Consultation

• Improve Clinical Research Literacy
  • Develop new educational content or utilize existing CISCRP resources
  • Videos, infographics, narrative or other modes of communication

• Ensure Usability and Clarity
  • CISCRP Health Communication Expert consultation
  • User review with target audience through CISCRP Editorial Panel
Thank you!

For more information:

**Contact us!**

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Chief Growth Officer
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**Follow us!**

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Appendix: Additional Tools and Resources
Tools and Resources

• Harvard MRCT
  • Health Literacy in Clinical Research website (case examples and links to resources)
  • Diversity in Clinical Trials Guidance & Toolkit
• EUPATI Guidance for Patient Involvement in Industry-led Medicines R&D
• Guidance: Patient Focused Medicines Development
  • Patient Engagement Quality Guidance (PEQG)
  • Patient Engagement Book of Good Practices
• Clinical Trials Transformation Initiative (CTTI)
  • Building Better Clinical Trials: A Case Study Exchange
  • Recommendations for Successful Collaborations with Patient Groups
• Health Literacy Solutions Center
Tools and Resources (continued)

- Harvard MRCT:
  - RoR Aggregate Results Guidance and Toolkit
  - Presenting Secondary Endpoints in Plain Language Clinical Trial Result Summaries
- European Commission: “How to Write Clearly”
- Trainings
  - CDC Health Literacy
  - NIH Plain Language
  - Tufts PL4H Health Literacy Workshops
  - PARADIGM: Working with Community Advisory Boards
Tools and Resources (continued)

European Commission: Lay Language Summaries Guidance

- EFPIA/EFGCP Good Summary Practices Guidance (Public Comment ended 9/12/20)
- Raynor et. al.: “Clinical Trial Results Summary for Laypersons: A User Testing Study”
- Summaries of Clinical Trial Results for Laypersons (EU Guidance)
- Transcelerate: Implementation Guide and Recommendations for Drafting
- Trialsummaries.com & Mytrialshub.com